UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,168	11/26/2003	Larry Eugene West	BROAD.028A	5738

20995 7590 08/01/2008

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
BOWERS, NATHAN ANDREW	
ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
08/01/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	10/723,168	WEST, LARRY EUGENE	
	Examiner	Art Unit	
	NATHAN A. BOWERS	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-11,16-34 and 38-42* is/are pending in the application.

4a) Of the above claim(s) *25-34 and 39* is/are withdrawn from consideration.

5)☒ Claim(s) *3,5-11,16-24,38 and 40-42* is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *030608, 050208, 070208*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Irwin (US 6385496) in view of Cannon (US 20050186671) and Zeitlin (EP 0156176).

Irwin discloses a system for controlling a plurality of different reactor processes in a plurality of reactors (Figure 1:100, 200, 300). The reactors are coupled to a controller (Figure 1:12) over a selected communication network (Figure 1:18). The controller receives information from the reactors, and determines a control signal based on data representing conditions within each reactor. This is disclosed in column 4, line 32 to column 5, line 41. A monitoring system transmits information related to a condition within the reactor and obtained by sensors (Figure 1:105, 205, 305) to the controllers via the utility tower. Computers (Figure 1:14) are additionally provided to accept input of a control command to change a desired condition within a reactor by

sending a command signal to the controller (Figure 1:12) over an additional network (Figure 1:15). Irwin, however, does not expressly indicate that a utility tower is used to transmit detected conditions within the reactors to the controller.

Cannon discloses a bioreactor system in which a plurality of bioreactor assembly cartridges (Figures 1-3) are positioned within a incubator rack (Figure 4). Each bioreactor assembly includes a media reservoir (Figure 6:22), a bioreactor (Figure 6:10) and at least one flow sensor (Figure 6:13). This is disclosed in paragraph [0052]. Cannon teaches in paragraph [0083] that data obtained by each of the sensors in each of the bioreactor assemblies is first sent to a utility tower in the form of an amplifier or a transmitter, and then it is sent a controller via a communication path or bus.

Zeitlin discloses a system for controlling a plurality of bioreactors (Figure 1:15) using controllers (Figure 1:10, 11, 12, 13). It is apparent that the controllers and the common master controller (Figure 1:20) are each housed separately from the bioreactors.

Irwin and Cannon are analogous art because they are from the same field of endeavor regarding control networks for multiple reactor systems.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to provide the system for controlling a plurality of different reactors disclosed by Irwin with a common utility tower means configured to sense conditions in the plurality of reactors. Cannon indicates in paragraph [0083] that it is known in the art to utilize amplifiers and transmitters as a utility tower to relay information between a controller and a bioreactor. Cannon suggests that the use of a transmitter is a common mechanism by which to send data to a local or remote

controller. The construction of control/utility towers separate from the physical structure of the bioreactor is considered to be well known in the art, as evidenced by Zeitlin.

The Irwin reference still differs from Applicant's claim invention because Irwin does not expressly disclose that the reactors are bioreactors.

As discussed above, Cannon discloses a bioreactor system in which culturing parameters such as temperature, dissolved gas concentration and glucose concentration are monitored.

Zeitlin discloses a system for controlling a plurality of bioreactors (Figure 1:15) using controllers (Figure 1:10, 11, 12, 13, 20). Zeitlin indicates on page 7, lines 21-28 and page 9, lines 1-27 that air flow, oxygen flow, agitator speed, foam, pH and temperature levels within the bioreactor are monitored and regulated using the controllers.

Irwin, Cannon and Zeitlin are analogous art because they are from the same field of endeavor regarding control networks for multiple reactor systems.

At the time of the invention, it would have been obvious to one of ordinary skill in the art that the control system disclosed by Irwin would be fully capable of regulating the operation of a plurality of bioreactors. It would have been apparent to use the system of Irwin to monitor and control certain parameters, such as agitation, temperature and fluid flow, that are critical to fermentation processes. As evidenced by Zeitlin and Cannon, it is well known in the art to regulate bioreactor systems using an automated controller.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2) Claims 1-24 and 38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 8-11, 14-22, 27 and 40-48 of copending Application No. 11/057079. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application is generic to Application No. 11/057079. Application No. 11/057079 includes all of the limitations presented in the instant application, such as the use of first, second and third communication networks, utility towers, and controllers to regulate the operation of a bioreactor system. Application No. 11/057079 is drawn to additional limitations regarding the use of the control system that are not presented in the claims of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

Claims 3, 5-11, 16-24, 38 and 40-42 are allowed.

With respect to independent claims 3 and 38, the prior art does not disclose, in the claimed environment, a bioreactor control system comprising a utility tower comprising a monitoring system that transmits information related to a condition of the bioreactor to a controller, a bioreactor supply system, and either an agitation system or temperature control system. The previously applied Zeitlin and Cannon references each teach that it is known to relay information from a reactor to a controller using a transmitting device. These references, however, do not disclose that the transmitting device is a separately housed utility tower that also is capable of supplying a substance to the bioreactors in response to the control signal. Furthermore, the prior art does not teach the use of a utility tower that comprises an agitation system, or a temperature control system capable of heating or cooling the bioreactors. The transmitting devices of the prior art simply convey information to and from the controller, and do not include physical fluid supply, agitation, and temperature control elements.

The Galliher (US 20080068920) reference describes relevant teachings regarding the use of a utility tower (see Figure 3), however Galliher is not prior art.

Response to Arguments

Applicant's arguments filed 02 May 2008 with respect to the 35 U.S.C. 103 rejections involving claims 1 and 2 have been fully considered, but are not persuasive.

The various control devices set forth in Irwin and Zeitlin are each arranged as separate, independently housed structures. Although the transmitter in Cannon is an integral component

of the bioreactor, it would have been obvious to provide the Cannon transmitting device as a separately housed tower in view of Irwin and Zeitlin. It is understood that the maintenance of this rejection is at odds with the understanding reached in the last interview (6/11/2008). The conversation of that meeting mostly involved Cannon's lack of disclosure regarding a separately housed utility tower. Upon further review, the Irwin and Zeitlin references each provide clear descriptions of independently formed control components, and, accordingly, it would have been apparent to likewise create a separately housed utility tower.

Applicant's arguments filed 02 May 2008 with respect to the 35 U.S.C. 103 rejections involving claims 3, 5-11, 16-24, 38 and 40-42 have been fully considered, and are persuasive. Accordingly, these rejections have been withdrawn.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/Nathan A Bowers/
Examiner, Art Unit 1797